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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,785	04/25/2006	John Nolting	PA1394	2982

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER
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HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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07/14/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/563,785</p>	<p><b>Applicant(s)</b> NOLTING, JOHN</p>	
	<p><b>Examiner</b> CARALYNNE HELM</p>	<p><b>Art Unit</b> 1615</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: \_\_\_\_\_.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/Caralynne Helm/  
Examiner, Art Unit 1615

/Juliet C Switzer/  
Primary Examiner, Art Unit 1634

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that figure 3 and paragraphs 38 and 40 provide written basis for the recitation that the therapeutic in a given coating is released "after the adjacent overlying timing coating has completely eroded." This argument is not persuasive. Figure 3 is described as depicting the release of therapeutic from the coated stent. While the arrow symbols in this figure clearly translate to a time lag due to the presence of the timing coatings, it is not clear that they represent the complete or partial erosion of these layers. While paragraphs 38 and 40 discuss the erosion of the timing coatings occurring before the release of therapeutic agent from the adjacent underlying coating, there is no statement or suggestion that the timing coating must be completely gone before the release of therapeutic agent commences.

Applicants also argue that the combination of Miller et al. and Sirhan et al. reference C (Sirhan C) does not render obvious the instant claims. These two references are relied upon in each of the rejections made under 35 USC 103(a). Applicants reiterate these arguments for each of these rejections and assert that additional references relied upon in the rejections do not remedy the supposed deficiencies of Miller et al. in view of Sirhan C. It was acknowledged that Miller et al. did not explicitly teach sequential delivery of its contained drugs. However, applicants suggest that the only mechanism by which the drugs are released is by diffusion through the barrier layers taught by Miller et al. This is not the case, since Miller et al. explicitly envisioned biodegradable polymers in these barrier layers. Such a material would erode over time, as occurs in the instant layers, thereby providing the same mechanism of delivery touted by applicants. In addition, Sirhan C teach a layered coating configuration with rate limiting barriers, which like the instant claims and Miller et al., are biodegradable. Sirhan C explicitly envisions such a configuration generating the sequential delivery of drugs from the layered system. Since Sirhan C teach simultaneous and/or sequential delivery of their drugs, the embodiment of sequential delivery is different than the embodiment with both sequential and simultaneous delivery. While applicants argue that delivery "exclusively and sequentially...without the release of the therapeutic agents from the other therapeutic coatings" is not embraced by these teachings, based on the definition of the word sequence (an action or event that follows another; the successive order of two or more things), the sequential delivery taught by Sirhan C meets the limitations of "sequentially without the release of the therapeutic agents from the other therapeutic coatings." The word "exclusively" was interpreted in the context of the therapeutics (e.g. a therapeutic being released exclusively meant only one therapeutic at a time...no simultaneous release) and was not viewed to alter the meaning of "sequentially without the release of the therapeutic agents from the other therapeutic coatings." In meeting the requirements for sequential release, the requirements for exclusive release were also met. Therefore the combination of Miller et al. and Sirhan C, along with the other cited references render obvious the instant claims.